SFDA

Safety communication

[17/03/2022]

Potential Risk of Psoriasis Associated with the Use of Dupilumab

The Saudi Food and Drug authority (SFDA) would like to notify healthcare professionals about the potential risk of psoriasis associated with the use of dupilumab.

The SFDA approved dupilumab for treatment of moderate-to-severe atopic dermatitis and as add-on maintenance treatment for severe asthma and chronic rhinosinusitis with nasal polyposis.

Psoriasis is an immune-mediated disease that causes inflammation in the bodythat may be associated with visible signs of the inflammation such as raised plaques and scales on the skin. Psoriasis can be triggered by gene mutation or environmental factors such as infections, stress, skin injury, hormone changes, weather, and certain medications.

We reviewed the published literature and post marketing databases to assess association between the potential risk of psoriasis with dupilumab use. Our review found three case series of eight patients and six published case reports suggesting a possible association between the psoriasis and dupilumab use. In addition, we identified 642 spontaneous case reports of psoriasis with dupilumab use in the World Health Organization (WHO) database, reported between 1999 and June 2021. Most reported cases were from the United States and 302 cases were serious. The cases involved 178 males and 251 females, and the rest of cases were unknown. Age ranges were varied between 9 to 91 years (316 cases were ≥ 18 years old, 20 cases were ≤18 years and the rest of cases were unknown). Time to onset in most cases ranged from one month up to 1 year following dupilumab use.

Therefore, the SFDA requests to update the product information of dupilumab containing products by adding psoriasis as post marketing adverse event.

Call for reporting:

The SFDA urges both healthcare professionals and patients to report ADRs related to use of any medication to the SFDA using the following contact information:
The National Pharmacovigilance Centre (NPC):
Fax: +966-11-205-7662 SFDA
Call Center: 19999
E-mail: npc.drug@sfda.gov.sa
Website: https://ade.sfda.gov.sa